Reporting Table
Research Involving Human Subjects

This table summarizes what must be reported to whom and when during the course of any human subject research conducted by, for, or at _____ National Laboratory. For details on reporting responsibilities and report content, contact the __NL IRB.

Who	Reports What	To Whom	When
PI	Any ***adverse event***[1]	IRB	within 1 week
	Any ***serious adverse event***[2]	IRB, sponsor	immediately
	Any ***unanticipated problem***[3]	IRB	within 2 weeks
	Deviation from approved protocol[4]	IRB	promptly
	Failure to comply with requirements[4]	IRB	
	Proposed change in approved protocol, including change of PI[5]	IRB	before change occurs – change must be approved by IRB
	Progress and status on active protocols[6]	IRB	annually
IRB	All serious adverse events[7]	DOE, sponsor	promptly
		OHRP	within 1 week
	All unanticipated problems[8]	__NL	promptly
		OHRP, sponsor	within 30 days of receiving PI report
	All ***serious*** or continuing ***non-compliances***[9]	__NL, DOE, OHRP, sponsor	promptly
	All suspensions or terminations of IRB approval of research[10]	PI, __NL, DOE, OHRP	promptly
	Any new proposal that includes:[11] • an institution without an established IRB • a foreign country • a potential for significant controversy • vulnerable populations *or* • classified or sensitive information	DOE	before IRB approval
	Changes in IRB membership[12]	DOE, OHRP	as they occur
	Complaints about research[13]	__NL, DOE	promptly
	Summary of approved research[14]	DOE	annually

DOE – Department of Energy Office of Science (SC-72) and local DOE Office
IRB – Institutional Review Board Administrator or IRB Office
OHRP –Office for Human Research Protections in the Department of Health and Human Services (DHHS)
PI – Principal Investigator
__NL – __NL Institutional Official

Definitions

Adverse event – Any undesirable incident, experience, or outcome associated with a subject's participation in the research, whether or not considered related to the research.

Serious adverse event – An adverse event that meets **any** of the following criteria

- results in death
- is life-threatening
- results in subject hospitalization
- results in persistent or significant disability/incapacity or other harm
- results in congenital anomaly/birth defect, or
- requires medical or surgical intervention to prevent one of the above outcomes

Noncompliance – Any failure to comply with applicable requirements (federal law, DOE directive, or IRB policy/procedure) to protect human subjects.

Serious noncompliance – A noncompliance is deemed serious if it affects the health, safety or well being of subjects, or if it constitutes a deviation from the IRB-approved protocol.

Continuing noncompliance – A noncompliance becomes continuing if it is repeated or additional noncompliances are associated with the same PI or organization.

Unanticipated problem -- Any incident, experience, or outcome associated with the subject's participation in the research that meets **all** of the following criteria:

(1) is unexpected given the research procedures and the subject population being studied

(2) is possibly related** to participation in the research

(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**there is a reasonable possibility this may have been caused by the research procedures

Examples

Unanticipated Problem

A PI conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the PI's car on the way home from work. This constitutes an unanticipated problem and must be reported because the incident was (a) unexpected (the PI did not anticipate the theft); (b) related to participation in the research; and (c) placed the subjects at a greater risk of harm from the breach in confidentiality of the study data than was previously known or recognized.

Adverse Event that is Not Unanticipated

A PI is conducting a psychology study to evaluate the factors that affect reaction times in response to auditory stimuli. To perform the reaction time measurements, subjects are placed in a small, windowless, soundproof booth and asked to wear headphones. The IRB-approved protocol and

informed consent document describe claustrophobic reactions as one of the risks of the research. The 20th subject enrolled experiences significant claustrophobia, resulting in the subject withdrawing from the research. This is not an unanticipated problem because the potential for claustrophobic reactions – in terms of nature, severity, and frequency – was expected and documented. This is reportable to the IRB, but not to DOE or OHRP.

Source of requirements identified in table

[1, 2, 3] 10 CFR 745.103(b)5, DOE 443.1A

[4] 10 CFR 745.103(b)5

[5] 10 CFR 745.103(b)4, DOE 443.1A

[6] DOE 443.1A

[7] 10 CFR 745.103(b)5, DOE 443.1A

[8] 10 CFR 745.103(b)4 and 5

[9] 10 CFR 745.103(b)5

[10] 10 CFR 745.103(b)4 and 5

[11] DOE 443.1A

[12] 10 CFR 745.103(b)3, DOE 443.1A

[13] DOE 443.1A

[14] DOE 443.1A

Notes

- This table does not include FDA requirements.
- Some reporting requirements depend on the funding source.
- These definitions are a compilation from several sources, including the OHRP Guidance issued 1/15/07.
- Most of the time frames for reporting come from that OHRP source also.
- Terms like “promptly” and “immediately” are a little vague, but still connote a limited time span. More clarification here is probably not in anyone’s best interest as these terms allow a bit of wiggle room for both PIs and IRBs while still conveying a sense of urgency.